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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,277	03/16/2004	Staley Brod	D5716CIP4/C	6125
52034 7590 04/12/2007 FULBRIGHT & JAWORSKI, L.L.P. 600 CONGRESS AVENUE SUITE 2400 AUSTIN, TX 78701			EXAMINER SEHARASEYON, JEGATHEESAN	
			ART UNIT 1647	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/12/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/801,277	BROD, STALEY	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/22/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Office acknowledges the receipt of the response filed on 1/4/2007. The Office also acknowledges the receipt of the preliminary amendment containing claims 19-30 on 3/16/2004. Applicant has amended claims 20, 24 and 28. Therefore claims 19-30 are pending and examined.

Specification

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

3. The use of the trademark Vectastain (p.50), Genius (p. 69) and Roferon (p.78) has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

4. The specification is objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID Nos. to all mentions of specific sequences in the specification and the claims. See 37 CFR § 1.821(d).

Priority

5. Applicant is required to update the priority information by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

6. Applicant is entitled to the priority date of 10/8/1997 (filing date of Application No. 08/946, 710) for a method of preventing destructive joint disease associated with

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rheumatoid arthritis, a method of reducing inflammation associated with rheumatoid arthritis and a method of reducing a level of interleukin in an individual with rheumatoid arthritis. However, the Applicant is entitled to the priority date of 4/12/1994 (filing date of Application No. 08/226, 631) for a method of treating rheumatoid arthritis.

Drawings

7. The drawings filed 3/16/2004 is acknowledged.

Information Disclosure Statement

8. The IDS filed 2/22/2005 has been considered.

Claim Rejections - 35 USC § 112, second paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21, 22, 25, 26, 27, 29 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9a. Claim 27 recites, "said decreasing the level" in claim 27 line 4. There is insufficient antecedent basis for this limitation in the claim. It is suggested that Applicant rewrite the claim to read ".....reducing the level of IL-1....."

9b. Claims 21, 22, 25, 26, 29 and 30 are rejected as being vague and indefinite because it is unclear if IFN- α or any human recombinant interferon is used in the methods of the instant invention.

9c. Claims 19- 30 are rejected as being vague and indefinite because it is unclear if IFN- α administered is in "international units" or "units". Further, it is not clear if

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the dosage administered is per Kg or total dose administered. The specification teaches that the dosage administered is 30,000 units.

Claim Rejections - 35 USC § 112, first paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10a. Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabling for treating destructive joint disease associated with rheumatoid arthritis in an individual or reducing inflammation associated with rheumatoid arthritis or reducing the level of interleukin in an individual with rheumatoid arthritis by oral administration of IFN- α , does not reasonably provide enablement for the preventing destructive joint disease associated with rheumatoid arthritis in an individual. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level

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of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Claims 19-22 are drawn to preventing destructive joint disease associated with rheumatoid arthritis by administering IFN- α orally. Applicant has shown in general there is improvement in the clinical indices (page 81). The prior art also teaches there is improvement in the clinical indices (Shiozawa et al., 1992). However, the specification as filed is insufficient to enable one of skilled in the art to practice the claimed invention of preventing destructive joint disease associated with rheumatoid arthritis without an undue amount of experimentation because the specification and the prior art have not prevented destructive joint disease associated with rheumatoid arthritis by administering IFN- α orally.

Applicant has not disclosed how to use the claimed invention to prevent destructive joint disease associated with rheumatoid arthritis by administering IFN- α orally of the subjects. There is insufficient evidence of the invention with respect to the *in vivo* operability of the claimed invention. Specifically, specification and prior art only teach the improvement of clinical indices and not the preventing destructive joint disease associated with rheumatoid arthritis. For example, the specification fails to provide guidance with respect to what patient population will be selected for the preventing destructive joint disease associated with rheumatoid arthritis by administering IFN- α . Also if a patient population with the "disease symptoms" are

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identified, the onset of disease has taken place, thus the pathology cannot be prevented (only further progression maybe stopped).

Since, there is inadequate guidance as to the nature of the invention, it is merely an invitation to the artisan to use the current invention as a starting point for further experimentation for preventing destructive joint disease associated with rheumatoid arthritis by administering IFN- α orally. In addition, because there are no working examples provided describing prevention of diseases or models it would require an undue amount of experimentation to one of skill in the art to practice the claimed invention.

Given the breadth of claims 19-22 in light of the unpredictability of the art as determined by the lack of working examples, the level of skill of the artisan, and the lack of guidance provided in the instant specification and the prior art of record, it would require undue experimentation for one of ordinary skill in the art to make and use the claimed invention for a method of preventing destructive joint disease associated with rheumatoid arthritis by administering IFN- α orally.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11a. Claims 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shozawa et al. (1992) in view of Cummings (U.S. Patent No: 4, 497, 795) and Cummings (U.S. Patent No: 5, 019, 382).

Claims are drawn to the oral administration of interferon-alpha for treating destructive joint disease associated with rheumatoid arthritis or reducing inflammation associated with rheumatoid arthritis.

Shozawa et al. disclose the administration of interferon alpha to treat rheumatoid arthritis (Table II, page 406). There is a reduction in swelling (inflammation). The reference also teaches that interferon-alpha therapy improves certain inflammatory indices of rheumatoid arthritis such as the joint score, C-reactive protein value and platelet count (p.406, column 2). Thus treating the destructive joint disease associated with rheumatoid arthritis. The reference also teaches that cytokines such as interleukin-1 (IL-1), IL-6 and tumor necrosis factor α play an important roles in the pathogenesis of rheumatoid arthritis (page 405). The reference does not teach dosage ranges described in the claims and the oral administration of IFN- α .

Cummings (U.S. Patent No: 4, 497, 795, Ref. A3 of PTO1449 dated 2/22/2005) teaches the oral administration of 5,000 to 50, 000 units of interferon per Kg body weight (see claim 15). This is equivalent to about 500 to 5000 IU/Kg. Cummings (U.S. Patent No: 5, 019, 382, Ref. A4 of PTO1449 dated 2/22/2005) describes that 1 unit \cong 0.1IU (column 3, lines 54-55). The reference also discloses a staggered regimen including one to three days treatment per week or month (column, 5, lines 53-55).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made to modify the interferon doses of Shozawa et al. (1992) to those taught by Cummings (U.S. Patent No: 4, 497, 795) and Cummings (U.S. Patent No: 5, 019, 382) with expectation of treating rheumatoid arthritis patients. One of ordinary skill in the art would have been motivated to use interferon in the doses recommended by Cummings et al (U.S. Patent No: 4, 497, 795) to treat rheumatoid arthritis with the expectation of success as because Cummings (U.S. Patent No: 5, 019, 382) teaches the treatment of autoimmune disorder, which includes rheumatoid arthritis (see column 5, lines 40-50). Therefore, the instant claims are *prima facie* obvious over Shozawa et al. (1992) in view of Cummings (U.S. Patent No: 4, 497, 795) and Cummings (U.S. Patent No: 5, 019, 382).

11b. Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shozawa et al. (1992) in view of Cummings (U.S. Patent No: 4, 497, 795) and Cummings (U.S. Patent No: 5, 019, 382) further in view of Aman et al. (1994).

Claims are drawn to the oral administration of interferon-alpha for reducing the level of interleukin in an individual with rheumatoid arthritis.

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The teachings of Shozawa et al. (1992) in view of Cummings (U.S. Patent No: 4, 497, 795) and Cummings (U.S. Patent No: 5, 019, 382) as been disclosed above in paragraph 10a. Although, Shozawa et al. teaches that cytokines such as interleukin-1 (IL-1), IL-6 and tumor necrosis factor α play an important roles in the pathogenesis of rheumatoid arthritis (page 405), it does not teach the reduction of interleukins following oral administration of interferon alpha.

Aman et al. (1994) teaches the reduction of interleukin-1 following the administration of Interferon alpha (see abstract, p.4147).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made to modify the teaching of Shozawa et al. (1992), Cummings (U.S. Patent No: 4, 497, 795) and Cummings (U.S. Patent No: 5, 019, 382) with the teachings of Aman et al. (1994) with the expectation of reducing the level of interleukin in an individual with rheumatoid arthritis. One of ordinary skill in the art would have been motivated to use interferon to treat rheumatoid arthritis as taught by Shiozawa et al. (1992) in the doses recommended by Cummings et al (U.S. Patent No: 4, 497, 795 and U.S. Patent No: 5, 019, 382) to reduce the level of interleukin in an individual with rheumatoid arthritis with the expectation of success because Aman et al. (1994) teaches that the administration of interferon alpha will reduce interleukin-1. Therefore, the instant claims are *prima facie* obvious over Shozawa et al. (1992) in view of Cummings (U.S. Patent No: 4, 497, 795) and Cummings (U.S. Patent No: 5, 019, 382) further in view of Aman et al. (1994).

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Conclusion

12. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
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April, 6, 2007.

Jegatheesan Seharaseyon
Patent Examiner